

K091267

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Vericom Co. Ltd.*Healthy and beautiful teeth with Vericom*

MAY - 6 2009

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: February 2, 2009

1. Company making the submission:

	Submitter
Name	VERICOM Co., Ltd.
Address	#606, 5 th Dongyoung Venturestel 199-32, Anyang 7-Dong, Manan-Gu Anyang-Si, Gyeonggi-Do, Republic of Korea 430-817
Phone	+82 31 441-2881
Fax	+82 31 441-2883
Contact	Myung-Hwan Oh
Internet	mh-oh@hanmail.net

2. Device:

Proprietary Name – Vonflex™ Putty
Common Name – Impression Materials
Classification Name – Material, Impression

3. Predicate Device:

Panasil putty soft, Kettenbach GmbH & Co. KG, K082560

4. Description:

Vonflex™ Putty, as the additional polymerization silicone type, is a rubber impression material that makes oral tissue shape precisely. And it is very easy to handle and has low shrinkage, helping to make precise impression taking.

5. Indication for use:

- Two step putty/wash impression technique
- One step putty/wash impression technique
- Two step putty/wash impression technique using a foil (plastic putty spacer)
- One step putty impression technique for forming functional peripheries

606, 5th Dongyoung Venturestel, 199-32, Anyang 7-dong, Manan-gu,
Anyang-si, Gyeonggi-do 430-817, Korea



Vericom Co. Ltd.

Healthy and beautiful teeth with Vericom

6. Review:

Vonflex™ Putty has the similar characteristics as the predicate device; Use concept, Flow properties, Setting time, and Compatibility with the die and cast materials.

Vonflex™ Putty has been subjected to extensive safety, performance, and product validations prior to release. Safety tests including biocompatibility have been performed to ensure the devices comply with the applicable International and US regulations.

7. Conclusions :

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification Vericom Co., Ltd. concludes that Vonflex™ Putty is safe and effective and substantially equivalent to predicate devices as described herein.

8. Vericom Co., Ltd. will update and include in this summary any other information deemed seasonably necessary by the FDA.

END



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY - 6 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Vericom Company, Limited
C/O Mr. Marc M. Mouser
Responsible Third Party Official
Underwriters Laboratories, Incorporated
2600 NW Lake Road
Camas, Washington 98607-9526

Re: K091267

Trade/Device Name: Vonflex™ Putty
Regulation Number: 21 CFR 872.3660
Regulatory Class: II
Product Code: ELW
Dated: March 20, 2009
Received: April 30, 2009

Dear Mr. Mouser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0100. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Susan Runner", with a stylized flourish at the end.

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K091267

000018

510(k) Submission – Vonflex™ Putty

510(k) Number K _____

Device Name: Vonflex™ Putty

Indication for use:

- Two step putty/wash impression technique
- One step putty/wash impression technique
- Two step putty/wash impression technique using a foil (plastic putty spacer)
- One step putty impression technique for forming functional peripheries

Prescription Use ☒ OR Over-The-Counter Use _____
(Per 21CFR801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Fugate
(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091267